IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAIHO PHARMACEUTICAL CO., LTD. and TAIHO ONCOLOGY, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ACCORD HEALTHCARE INC. and INTAS PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. (collectively, "Taiho" or "Plaintiffs"), for their Complaint for Patent Infringement and Declaratory Judgment against Defendants Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. (collectively, "Accord" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Taiho Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-27 Kandanishiki-cho, Chiyoda-ku, Tokyo 101-8444, Japan.

2. Plaintiff Taiho Oncology, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 101 Carnegie Center, Suite 101, Princeton, New Jersey 08540.

3. Upon information and belief, Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703-8446.

4. Upon information and belief, Accord Healthcare Inc. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd. Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the Republic of India having a principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

5. Upon information and belief, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. are in the business of, *inter alia*, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including the State of Delaware. In furtherance of such business, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. are agents of each other and/or work in active concert with each other, either directly or through one or more of their wholly owned subsidiaries.

6. Upon information and belief, Intas Pharmaceuticals Ltd. is in the business of, *inter alia*, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and subsidiaries, including

Accord Healthcare Inc., from which Intas Pharmaceuticals Ltd. derives a substantial portion of its revenue.

7. Upon information and belief, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. acted in concert to prepare and submit Accord's Abbreviated New Drug Application ("ANDA") No. 214036 (tipiracil HCl/trifluridine oral tablets) ("Accord's ANDA Product") to the United States Food and Drug Administration ("FDA").

8. Upon information and belief, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Accord's ANDA Product, and enter into agreements with each other that are nearer than arm's length.

9. Upon information and belief, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. participated in, assisted, and cooperated in the acts complained of herein.

10. Upon information and belief, following any FDA approval of Accord's ANDA, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. will act in concert to manufacture, market, distribute, and/or sell Accord's ANDA Product throughout the United States, including within the State of Delaware.

11. Accord and Taiho are currently involved in a related litigation in this Judicial District that relates to ANDA No. 214036, *Taiho Pharm. Co., Ltd., et al. v.*

Accord Healthcare Inc., C.A. No. 19-2321 (CFC). In the related litigation, Accord Healthcare Inc. agreed to not contest, *inter alia*, jurisdiction and venue in this district, and Intas Pharmaceuticals Ltd. agreed to be bound by any judgment or order, including any injunction, rendered with respect to Accord Healthcare Inc. as if Intas Pharmaceuticals Ltd. were a defendant. *Id.* at D.I. 10.

NATURE OF THE ACTION

12. This is a civil action for infringement of U.S. Patent No. 10,960,004 B2 ("the '004 patent") arising under the United States Patent Laws, Title 35, United States Code § 100, *et seq.*, and in particular under § 271, as well as a civil action for declaratory judgment of patent infringement of the '004 patent under 28 U.S.C. §§ 2201-02. Taiho seeks declaratory relief, injunctive relief, attorneys' fees, and any other relief the Court deems just and proper.

13. This action relates to ANDA No. 214036, which Accord filed or caused to be filed under 21 U.S.C. § 355(j) with the FDA, for approval to manufacture, use, and/or offer for sale a generic copy of Taiho's Lonsurf® (trifluridine and tipiracil) tablets throughout the United States prior to the expiration of the '004 patent.

JURISDICTION AND VENUE

14. This is a civil action for infringement arising under the United States Patent Laws, including 35 U.S.C. § 271, as well as a civil action for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201-02.

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201-02.

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

17. This Court has personal jurisdiction over Accord Healthcare Inc. because, *inter alia*, Accord Healthcare Inc., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Accord's ANDA Product to the residents of the State of Delaware; (3) purposely availed itself of the benefits and protections of Delaware's laws; and/or (4) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

18. Upon information and belief, Accord Healthcare Inc. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

19. Upon information and belief, Accord Healthcare Inc. has substantial, continuous, and systematic contacts with the State of Delaware, including Accord Healthcare Inc.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

20. Upon information and belief, Accord Healthcare Inc., and/or its subsidiaries, affiliates, or agents, intends to engage in the commercial manufacture and sale of Accord's ANDA Product, if approved by the FDA, before the expiration of the '004 patent throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

21. Upon information and belief, Accord Healthcare Inc., and/or its subsidiaries, affiliates, or agents, intends to place Accord's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

22. Upon information and belief, Accord Healthcare Inc. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

23. Additionally, the business of Accord Healthcare Inc. involves challenging patents held by branded pharmaceutical companies, including in the State of Delaware.

24. Accord Healthcare Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in at least the following matters: *Genentech, Inc. v. Accord Healthcare Inc.*, C.A. No. 19-142-

RGA; *Biogen Int'l GmbH et al v. Accord Healthcare Inc.*, C.A. No. 17-872-MN; *Bristol-Myers Squibb Co. v. Accord Healthcare Inc.*, C.A. No. 17-398-LPS; and *Cephalon Inc. v. Sandoz Inc. et al.*, C.A. No. 15-178-GMS.

25. Upon information and belief, Accord Healthcare Inc. participated in the preparation, development, and filing of ANDA No. 214036, and its underlying subject matter, with the intent to market, sell, and/or distribute Accord's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Accord Healthcare Inc.'s contact with the State of Delaware.

26. Venue is proper in this Judicial District as to Accord Healthcare Inc. because, *inter alia*, if approved, Accord Healthcare Inc. intends to market and sell Accord's ANDA Product in the State of Delaware and Accord Healthcare Inc. has repeatedly consented to being a defendant in this Judicial District.

27. This Court has personal jurisdiction over Intas Pharmaceuticals Ltd. because, *inter alia*, Intas Pharmaceuticals Ltd., upon information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Accord's ANDA Product to the residents of the State of Delaware; (3) owns subsidiary companies that are organized under the laws of the State of Delaware; (4) maintains a broad distribution network within the State of Delaware; and/or (5) enjoys substantial income from sales of its generic pharmaceutical products in the State of Delaware.

28. Upon information and belief, Intas Pharmaceuticals Ltd. has purposely availed itself of this forum by making, using, importing, selling, or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

29. Upon information and belief, Intas Pharmaceuticals Ltd. has substantial, continuous, and systematic contacts with the State of Delaware, including Intas Pharmaceuticals Ltd.'s engagement in the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

30. Upon information and belief, Intas Pharmaceuticals Ltd., and/or its subsidiaries, affiliates, or agents, intends to engage in the commercial manufacture and sale of Accord's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

31. Upon information and belief, Intas Pharmaceuticals Ltd., and/or its subsidiaries, affiliates, or agents, intends to place Accord's ANDA Product into the stream of commerce with the reasonable expectation or knowledge, and the intent, that such product will be purchased and used by consumers in this Judicial District.

32. Upon information and belief, Intas Pharmaceuticals Ltd. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in the State of Delaware, and/or derives substantial revenue from the services or products used or consumed in the State of Delaware.

33. Intas Pharmaceuticals Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, including by having asserted counterclaims in this jurisdiction in the matters of: *Cephalon Inc. v. Sandoz Inc. et al.*, C.A. No. 15-178-GMS and *Pfizer Inc. et al v. Intas Pharmaceuticals Ltd.*, C.A. No. 11-1253-GMS.

34. Upon information and belief, Intas Pharmaceuticals Ltd. participated in the preparation, development, and filing of ANDA No. 214036, and its underlying subject matter, with the intent to market, sell, and/or distribute Accord's ANDA Product to the residents of the State of Delaware. Taiho's causes of action arise from Intas Pharmaceuticals Ltd.'s contact with the State of Delaware.

35. Venue is proper in this Judicial District as to Intas Pharmaceuticals Ltd. because, *inter alia*, Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this Judicial District.

LONSURF®

36. Plaintiff Taiho Oncology, Inc. is the holder of the New Drug Application ("NDA") No. 207981 for the manufacture and sale of trifluridine and tipiracil tablets, 15mg and 20 mg, and sells the product in the United States under the registered trademark Lonsurf®.

37. The FDA approved NDA No. 207981 for the 15mg and 20mg tablets on September 22, 2015.

38. Plaintiff Taiho Oncology, Inc. sells and distributes Lonsurf®, including through wholesalers, throughout the United States pursuant to NDA No. 207981.

39. Lonsurf® is indicated for the treatment of metastatic colorectal cancer that has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy as well as the treatment of metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. A copy of the December 2019 Lonsurf® Label is attached as Exhibit A.

PATENT-IN-SUIT

40. U.S. Patent No. 10,960,004 ("the '004 patent), entitled "Method for Treating Cancer Patients with Severe Renal Impairment" was duly and legally

reissued by the United States Patent and Trademark Office ("USPTO") on March 30, 2021. Taiho Pharmaceutical Co., Ltd. is the owner of all the right, title, and interest in and to the '004 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '004 patent is attached as Exhibit B.

41. Pursuant to the Federal Food, Drug, and Cosmetic Act ("FFD&C Act"), 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Taiho has submitted information concerning the '004 patent to the FDA in connection with NDA No. 207981, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '004 patent has been listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Lonsurf®.

42. Claim 1 of the '004 patent is directed, *inter alia*, to a method for treating gastrointestinal cancer, large bowel cancer, and/or breast cancer comprising: orally administering a drug comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-[(2-iminopyrrolidine-1-yl)methyl]pyrimidine-2,4(1H,3H)-dione hydrochloride in a molar ratio of 1:0.5, at a daily dose of 30 to 40 mg/m^2/day

as FTD-equivalent, in two to four doses a day to the patient with a creatinine clearance of 15 mL/min-29 mL/min.

43. The approved Lonsurf® product labeling instructs medical personnel when treating patients with severe renal impairment and/or patients with severe renal impairment to perform the steps of at least one claim of the '004 patent.

44. The use of Lonsurf® by patients with, and/or by medical personnel in accordance with, its approved product labeling, necessarily results in the performance of each step of at least one claim of the '004 patent.

ACCORD'S ANDA PRODUCT

45. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. § 355(j), Accord submitted ANDA No. 214036 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's ANDA Product within the United States prior to the expiration of the '004 patent.

46. Upon information and belief, Accord's ANDA No. 214036 identified Taiho's Lonsurf® (trifluridine and tipiracil) tablets and includes a written certification, as required by FFD&C Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the '004 patent are invalid or otherwise will not be infringed by Accord's ANDA Product.

47. On or about April 28, 2021, Taiho received a letter from Accord purporting to be a written notice that Accord had filed ANDA No. 214036 seeking approval to market Accord's ANDA Product prior to the expiration of the '004 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV notice letter"). The Paragraph IV notice letter included notice of Accord's allegations that the '004 patent is invalid and/or not infringed by Accord's ANDA Product.

48. Accord's submission of ANDA No. 214036, including the Paragraph IV certification, to the FDA constituted infringement of the '004 patent under 35 U.S.C. § 271(e)(2).

49. Accord's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Accord's ANDA Product upon approval of ANDA No. 214036 and before expiration of the '004 patent will infringe at least claim 1 of the '004 patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. Taiho commenced this action fewer than 45 days after receiving Accord's Paragraph IV notice letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 10,960,004

51. Paragraphs 1-50 are incorporated by reference as though fully set forth herein.

52. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets to patients with severe renal impairment according to the Lonsurf® product labeling satisfies at least claim 1 of the '004 patent.

53. Upon information and belief, Accord's ANDA Product has the same use as Lonsurf®, at least because Accord's ANDA No. 214036 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

54. Upon information and belief, the proposed product labeling for Accord's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

55. Upon information and belief, Accord's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

56. Upon information and belief, Accord's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '004 patent.

57. Accord's submission of ANDA No. 214036 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Accord's ANDA Product prior to the expiration of the '004 patent constitutes infringement of at least claim 1 of the '004 patent under 35 U.S.C. § 271(e)(2).

58. Claim 1 of the '004 patent recites "A method for treating gastrointestinal cancer, large bowel cancer or breast cancer in a patient with a creatinine clearance of 15 mL/min-29 mL/min, comprising: orally administering a drug comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-[(2-iminopyrrolidine-1-yl)methyl]pyrimidine-2,4(1H,3H)-dione hydrochloride in a molar ratio of 1:0.5, at a daily dose of 30 to 40 mg/m^2/day as FTD-equivalent, in two to four doses a day to the patient with a creatinine clearance of 15 mL/min-29 mL/min."

59. Discovery will likely show that the product labeling for Accord's ANDA Product will instruct medical personnel and/or patients to treat gastrointestinal cancer and/or large bowel cancer in patients with a creatinine clearance of 15 mL/min-29 mL/min by orally administering a drug comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-[(2-iminopyrrolidine-1-yl)methyl]pyrimidine-2,4(1H,3H)-dione hydrochloride in a molar ratio of 1:0.5, at a daily dose of 30 to 40 mg/m^2/day as FTD-equivalent, in two to four doses a day to the patient with a creatinine clearance of 15 mL/min-29 mL/min. Discovery will also likely show that the proposed product labeling for Accord's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

60. Upon information and belief, upon the FDA's approval of ANDA No. 214036, Accord will infringe at least claim 1 of the '004 patent under 35 U.S.C. §

271(a) by making, using, selling, offering to sell, or importing Accord's ANDA Product in the United States.

61. Upon information and belief, upon the FDA's approval of ANDA No. 214036, Accord will infringe at least claim 1 of the '004 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '004 patent, with knowledge of said patent and said infringement.

62. Upon information and belief, the proposed product labeling for Accord's ANDA will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the '004 patent.

63. Upon information and belief, the use of Accord's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '004 patent.

64. Upon information and belief, Accord specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Accord knows infringe at least claim 1 of the '004 patent.

65. Upon information and belief, upon the FDA's approval of ANDA No. 214036, Accord will infringe at least claim 1 of the '004 patent under 35 U.S.C. § 271(c) by selling or offering to sell Accord's ANDA Product in the United States,

with knowledge of the '004 patent and that there is no substantial non-infringing use of Accord's ANDA Product.

66. Upon information and belief, Accord knows that Accord's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claim 1 of the '004 patent.

67. Accord's ANDA Product constitutes a material part of the invention covered by at least claim 1 of the '004 patent.

68. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 214036 shall be no earlier than the date on which the '004 patent expires, including any patent term and regulatory extensions.

69. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Taiho is entitled to a permanent injunction against further infringement. Taiho will be substantially and irreparably harmed if Accord's infringement of the '004 patent is not enjoined. Further, Taiho does not have an adequate remedy at law.

70. Upon information and belief, Accord was aware of the '004 patent prior to Accord submitting its Paragraph IV certification as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without reasonable basis for a good faith belief that it would not be liable for infringing the '004 patent.

COUNT II – DECLARATORY JUDGMENT FOR INFRINGEMENT OF U.S. PATENT NO. 10,960,004

71. Paragraphs 1-70 are incorporated by reference as though fully set forth herein.

72. Administration of Taiho's Lonsurf® (trifluridine and tipiracil) tablets to patients with severe renal impairment according to the Lonsurf® product labeling satisfies at least claim 1 of the '004 patent.

73. Upon information and belief, Accord's ANDA Product has the same use as Lonsurf®, at least because Accord's ANDA No. 214036 refers to and relies upon Taiho's NDA No. 207981 for Lonsurf®.

74. Upon information and belief, the proposed product labeling for Accord's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

75. Upon information and belief, Accord's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Lonsurf®.

76. Upon information and belief, Accord's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '004 patent.

77. Accord's submission of ANDA No. 214036 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Accord's ANDA Product prior to the expiration of the '004 patent

constitutes infringement of at least claim 1 of the '004 patent under 35 U.S.C. § 271(e)(2).

78. Claim 1 of the '004 patent recites "A method for treating gastrointestinal cancer, large bowel cancer or breast cancer in a patient with a creatinine clearance of 15 mL/min-29 mL/min, comprising: orally administering a drug comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-[(2-iminopyrrolidine-1-yl)methyl]pyrimidine-2,4(1H,3H)-dione hydrochloride in a molar ratio of 1:0.5, at a daily dose of 30 to 40 mg/m^2/day as FTD-equivalent, in two to four doses a day to the patient with a creatinine clearance of 15 mL/min-29 mL/min."

79. Discovery will likely show that the product labeling for Accord's ANDA Product will instruct medical personnel and/or patients to treat gastrointestinal cancer and/or large bowel cancer in patients with a creatinine clearance of 15 mL/min-29 mL/min by orally administering a drug comprising α,α,α-trifluorothymidine (FTD) and 5-chloro-6-[(2-iminopyrrolidine-1-yl)methyl]pyrimidine-2,4(1H,3H)-dione hydrochloride in a molar ratio of 1:0.5, at a daily dose of 30 to 40 mg/m^2/day as FTD-equivalent, in two to four doses a day to the patient with a creatinine clearance of 15 mL/min-29 mL/min. Discovery will also likely show that the proposed product labeling for Accord's ANDA Product is substantially the same as the approved product labeling for Lonsurf®.

80. Upon information and belief, upon the FDA's approval of ANDA No. 214036, Accord will infringe at least claim 1 of the '004 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Accord's ANDA Product in the United States.

81. Upon information and belief, upon the FDA's approval of ANDA No. 214036, Accord will infringe at least claim 1 of the '004 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '004 patent, with knowledge of said patent and said infringement.

82. Upon information and belief, the proposed product labeling for Accord's ANDA will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the '004 patent.

83. Upon information and belief, the use of Accord's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '004 patent.

84. Upon information and belief, Accord specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Accord knows infringe at least claim 1 of the '004 patent.

85. Upon information and belief, Accord was aware of the '004 patent prior to Accord submitting its Paragraph IV certification as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95.

86. Upon information and belief, Accord acted, and upon the FDA's approval of ANDA No. 214036, will act, without a reasonable basis for a good faith belief that it would not be liable for directly and indirectly infringing the '004 patent.

87. Upon information and belief, upon the FDA's approval of ANDA No. 214036, Accord will infringe at least claim 1 of the '004 patent under 35 U.S.C. § 271(c) by selling or offering to sell Accord's ANDA Product in the United States, with knowledge of the '004 patent and that there is no substantial non-infringing use of Accord's ANDA Product.

88. Upon information and belief, Accord knows that Accord's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing at least claim 1 of the '004 patent.

89. Upon information and belief, Accord was aware of the '004 patent prior to Accord submitting its Paragraph IV certification as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95.

90. Pursuant to 28 U.S.C. § 2201, Taiho is entitled to a declaratory judgment that Accord's making, using, offering to sell, selling and/or importing

Accord's ANDA Product, inducement thereof, or contribution thereto, will infringe the '004 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c).

91. Pursuant to 28 U.S.C. § 2201 and 35 U.S.C. § 271(e)(4)(A), Taiho is entitled to a declaratory judgment that the effective date of any approval of ANDA No. 214036 shall be no earlier than the date on which the '004 patent expires, including any patent term and regulatory extensions.

92. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Accord's ANDA Product with its proposed labeling, or any other Accord drug that is covered by or whose use is covered by the '004 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '004 patent, and that the claims of the '004 patent are not invalid.

REQUEST FOR RELIEF

WHEREFORE, Taiho respectfully requests the following relief:

A. The entry of judgment on the Complaint in favor of Plaintiffs and against Defendant.

B. The entry of judgment that Accord has infringed the '004 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214036 to the FDA;

C. The entry of judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Accord's ANDA Product before the expiration of the '004 patent including any patent term and regulatory extensions will constitute acts of infringement of the '004 patent by Accord;

D. The issuance of an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 214036 shall be no earlier than the date on which the '004 patent expires, including any patent term and regulatory extensions;

E. The issuance of an injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, enjoining Accord, its officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the '004 patent prior to the expiration of said patent including any patent term and regulatory extensions;

F. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) and/or 35 U.S.C. § 284 as appropriate;

G. A finding that this is an exceptional case under 35 U.S.C. § 285, and an award to Taiho of its reasonable attorneys' fees and costs; and

H. An award of any such other and further relief as the Court may deem just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

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